



Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, FL 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-06-29

July 10, 2006

Jeffery B. Pasch, President
Jeff's Gourmet Pies, Inc.
6704 Parke East Boulevard
Tampa, Florida 33610-4145

Dear Mr. Pasch:

On March 2, 2006, the Food and Drug Administration (FDA) conducted an inspection of your plant located at the above address. During the inspection, we collected labeling for some of your products. Our review of this labeling found serious violations of the Federal Food, Drug, and Cosmetic Act (the Act) and FDA's implementing regulations in Title 21, Code of Federal Regulations (21 CFR), Part 101, Food Labeling. You can find the Act and FDA regulations through links in FDA's homepage at www.fda.gov.

Ingredient labeling

Your Plain Cheesecake, Triple Chocolate Supreme Layer Cake, and Cookies & Cream Ice Cream Pie products are misbranded within the meaning of section 403(i)(2) of the Act [21 U.S.C. 343(i)(2)] because they are fabricated from two or more ingredients and their labels fail to declare the common or usual name of each ingredient as required by 21 CFR 101.4. The label of a product is defined in section 201(k) of the Act [21 U.S.C. 321(k)] as "a display of written, printed, or graphic matter upon the immediate container of any article" The unit cartons of your Plain Cheesecake, Triple Chocolate Supreme Layer Cake, and Cookies & Cream Ice Cream Pie are the immediate containers of these products, and therefore the unit carton is the product label where the ingredient statement must appear along with the other information displayed there. None of these three products bears an ingredient statement on the unit carton.

We remind you that under 21 CFR 101.4(b)(2), all component ingredients of ingredients used in a finished food must themselves be declared in the ingredient statement of the finished food. For example, according to the product fact sheet collected during our inspection, your Plain Cheesecake contains vanilla cookie crumbs and cream cheese. Both of these ingredients are multi-component foods; e.g., the vanilla cookie crumbs contain sugar, vegetable shortening, dextrose, lecithin, salt, baking soda, flour, corn syrup, vanilla flavor, and butter flavor. For ingredients like vanilla cookie crumbs and cream cheese that themselves consist of multiple ingredients, the requirement to list their component ingredients (which are "sub-ingredients" of the finished food) may be met by either parenthetically listing the component ingredients after the common or usual name of the multi-component ingredient, or by listing the component ingredients without listing the multi-component ingredient itself [see 21 CFR 101.4(b)(2)]. Under the first alternative, the component ingredients must be listed in descending order of predominance within the multi-component ingredient; and under the second alternative, the component ingredients must be listed in descending order of predominance in the finished food.

Some of your products contain undeclared allergenic ingredients. Undeclared ingredients that are known allergens are of particular concern to the agency. FDA has received an increasing number of reports concerning consumers who have experienced adverse reactions following exposure to an allergenic substance in foods. For sensitive individuals, the presence of allergens in food is potentially life threatening. Ingredients that are among the most commonly known to cause serious allergic responses are milk, eggs, fish, crustaceans, tree nuts, wheat, peanuts, soybeans, and derivatives of these products.

Allergen source labeling

Your Plain Cheesecake, Triple Chocolate Supreme Layer Cake, and Cookies & Cream Ice Cream Pie products are further misbranded within the meaning of section 403(w) of the Act [21 U.S.C. 343(w)] in that the labels fail to declare all major food allergens present in those products, as required by section 403(w)(1). Section 201(qq) of the Act [21 USC 321(qq)] defines as major food allergens milk, egg, fish, Crustacean shellfish, tree nuts, wheat, peanuts, and soybeans, as well as any food ingredient that contains protein derived from one of these foods, with the exception of highly refined oils. A food is misbranded if it is not a raw agricultural commodity and it is, or it contains an ingredient that bears or contains, a major food allergen, unless either:

- (1) The word "Contains," followed by the name of the food source from which the major food allergen is derived, is printed immediately after or adjacent to the list of ingredients (section 403(w)(1)(A) of the Act [21 U.S.C. 343(w)(1)(A)]), or

- (2) The common or usual name of the major food allergen in the list of ingredients is followed in parentheses by the name of the food source from which the major food allergen is derived, except that the name of the food source is not required when either the common or usual name of the ingredient uses the name of the food source or the name of the food source appears elsewhere in the ingredient list (unless the name of the food source that appears elsewhere in the ingredient list appears as part of the name of an ingredient that is not a major food allergen) (section 403(w)(1)(B) of the Act [21 U.S.C. 343(w)(1)(B)]).

Your food labels fail to declare the following major food allergens as specified by the Act:

- Your Plain Cheesecake product contains milk, which is a component of the cream cheese ingredient, and eggs. According to the formulation information we obtained, your product also contains flour. If the flour is made from wheat, your label must also declare "wheat" as required by the Act.
- Your Triple Chocolate Supreme Layer Cake product contains milk and soy, which are components of the artificially flavored vanilla non-dairy icing and filling ingredient, and eggs and pecans. According to the formulation information we obtained, your product also contains bread flour. If the bread flour is made from wheat, your label must also declare "wheat" as required by the Act.
- Your Cookies & Cream Ice Cream Pie product contains milk and soy, which are components of the margarine ingredient. According to the formulation information we obtained, the chocolate cookie crumbs used in this product contain flour. If the flour is made from wheat, your label must also declare "wheat" as required by the Act.

Other labeling violations

Your Plain Cheesecake, Triple Chocolate Supreme Layer Cake, and Cookies & Cream Ice Cream Pie products are further misbranded under section 403(e)(2) of the Act [21 U.S.C. 343(e)(2)] because the product labels fail to declare the net quantity of contents [see 21 CFR 101.105]. In addition, the Plain Cheesecake is misbranded under section 403(e)(1) of the Act because the product label fails to specify the place of business of the manufacturer, packer, or distributor [see 21 CFR 101.5].

The above violations are not meant to be an all-inclusive list of deficiencies in your products and their labeling. It is your responsibility to ensure that all of your products are in compliance with applicable statutes and regulations. You should take prompt action to correct these violations. You should also review the labeling of all your products, take corrective action where appropriate, and establish procedures whereby such violations do not recur. Failure to correct

these violations may result in regulatory action without further notice, including seizure and/or injunction.

Please notify this office in writing within fifteen (15) working days from the date you receive this letter of the steps you have taken to correct violations. For corrections that you cannot complete within the 15 working days, state the reason for the delay and your timeframe for completion. Please provide documentation of the corrections as they are made, including copies of any revised labels, and inform us of your plan for preventing similar violations in the future.

In addition to the violations described above, FDA has several comments concerning the labeling of your products. We note that the shipping containers for the cheesecake and ice cream pie products include a partial list of ingredients. You are not required to include an ingredient statement on these containers, but if you choose to do so, it must be a complete and accurate list of all product ingredients, including sub-ingredients.

For your information when revising your product labels, the ingredients of a food must be listed by common or usual name and without intervening material [21 CFR 101.2(e) and 101.4(a)(1)]. Further, promotional terms such as "fresh" (see, e.g. "fresh cream," listed as an ingredient on the shipping container of Cookies & Cream Ice Cream Pie) are not part of the common or usual name of the ingredient to which they refer; rather, they are considered intervening material and should not be included in the ingredient statement. For more information about common or usual names of food ingredients, please refer to 21 CFR 101.4(b)-(d) and 21 CFR 102.5. We suggest that you review the labels of all your products to ensure that they comply with the applicable requirements.

Please send your reply to the Food and Drug Administration, Attention: Brant M. Schroeder, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida, 32751. If you have any questions regarding this letter, please contact Mr. Schroeder at (407) 475-4763.

Sincerely,

A handwritten signature in black ink, appearing to read "Emma R. Singleton", with a long horizontal flourish extending to the right.

Emma R. Singleton
Director, Florida District